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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,415	01/26/2005	Vivian I Teichberg	29147	5568

7590 04/04/2006

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EXAMINER

GOUGH, TIFFANY MAUREEN

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/522,415	Applicant(s) TEICHBERG, VIVIAN I	
	Examiner Tiffany M. Gough	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-119 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-119 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-28, drawn to a method of reducing extracellular brain glutamate levels.

Group II, claim(s) 29-56, drawn to a pharmaceutical composition for reducing extracellular brain glutamate levels

.Group III, claim(s) 57-59, drawn to an additional pharmaceutical composition for reducing extracellular brain glutamate levels comprising pyruvate and oxaloacetate as active ingredients.

Group IV, claim(s) 60, drawn to a method of manufacturing a medicament.

Group V, claim(s) 61, drawn to a method of treating a disease.

Group VI, claim(s) 62-89,118, drawn to an article of manufacture comprising packaging material and a pharmaceutical composition.

Group VII, claim(s) 90-117, drawn to an additional method of reducing extracellular brain glutamate levels comprising obtaining a blood sample.

Group VIII, claim(s) 119, drawn to an additional pharmaceutical composition for .
composition for reducing extracellular brain glutamate levels comprising oxaloacetate
diethylester as an active ingredient.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: A “special technical feature” is defined by PCT Rule 13.2 as “those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.” In the instant case, as discussed below, a number of the claimed inventions fail to make any contribution over the prior art. Because a number of the claimed inventions fail to make any contribution over the prior art, the claims as filed fail to contain a single common special technical feature supporting a showing unity of invention.

Specifically, as demonstrated in the International Preliminary Examination Report (translated version) of the PCT parent of this application, Matthews et al , Journal of Neurochemistry, 2000 demonstrate that the inventions described in claims 1-119 lack novelty and inventive step. Because those claims fail to make a contribution over the prior art, it is clear that all claims as filed fail to provide special technical feature common to all claimed inventions. Because the claims as filed lack a common special technical feature, the claims lack unity.

Lack of a common special technical feature, and therefore lack of unity, is further demonstrated by the fact that the various products claimed, enzymes, substrates/co-factors and agents all have vastly different properties. Moreover, because the various processes recited in the claims recite different process steps, it is clear that the process claim also lack a single common special technical feature, and therefore also lack unity.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- a). glutamate modifying enzymes in claims 3 ,31,64 and 92
- b). transaminase in claims 4 ,32,65 and 93
- c). co-factors in claims 11,39,58,72 and 100
- d). agents in claims 15 ,43,76 and 104
- e). inhibitors in claims 28 ,56,89 and 118
- f). medical conditions in claim 61

Applicant is required, in reply to this action, to elect a single species from each of (a-f) to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Group I corresponds to claims 3,4,11,15 and 28
Group II corresponds to claims 31,32,39,43 and 56
Group III corresponds to claims 58
Group V corresponds to claims 61
Group VI corresponds to claims 64,65,72,76,89 and 118
Group VII corresponds to claims 92,93,100,104

The following claim(s) are generic: 1,29,57,60,62,90 and 119.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: A "special technical feature" is defined by PCT Rule 13.2 as "those technical features that define a contribution which each of the claimed species, considered as a whole, makes over the prior art." In the instant case, as discussed below, a number of the claimed species fail to make any contribution over the prior art. Because a number of the claimed species fail to make any contribution over the prior art, the claims as filed fail to contain a single common special technical feature supporting a showing unity of invention.

Specifically, as demonstrated in the International Preliminary Examination Report (translated version) of the PCT parent of this application, Matthews et al , Journal of

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Neurochemistry, 2000 demonstrate that the species described in claims 3-6, 10, 11, 28, 31-34, 38, 39, 56, 58, 61, 64, 65-67, 72 and all repetitive species lack novelty and inventive step. Because those claims fail to make a contribution over the prior art, it is clear that all claims as filed fail to provide special technical feature common to all claimed inventions. Because the claims as filed lack a common special technical feature, the claims lack unity.

Lack of a common special technical feature, and therefore lack of unity, is further demonstrated by the fact that the various products claimed, enzymes, substrates/co-factors and agents all have vastly different properties. Moreover, because the various processes recited in the claims recite different process steps, it is clear that the process claim also lack a single common special technical feature, and therefore also lack unity.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tiffany M. Gough whose telephone number is 571-272-0697. The examiner can normally be reached on M-F 8-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tmg



FRANCISCO PRATS
PRIMARY EXAMINER